PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Krivitski, Nikolai M. and Drost, Cornelis J.	Atty. Docket:	86017.000010
Serial No.:	09/419,849	Examiner:	Charlene Dickens
Filed:	October 19, 1999	Art Unit:	2855
Title:	METHOD AND APPARATUS TO MEASURE BLOOD FLOW BY AN INTRODUCED VOLUME CHANGE		

APPELLANTS' SUPPLEMENTAL APPEAL BRIEF

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Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

1. REAL PARTY IN INTEREST

The real party in interest is the assignee, Transonic Systems, Inc., 34 Dutch Mill Road, Ithaca, New York 14850.

2. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to appellants, the appellants' legal representative, or assignee which will affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

3. STATUS OF CLAIMS

All the pending claims in the application, Claims 1-38, stand rejected and are subject to the present appeal.

4. STATUS OF AMENDMENTS

An Amendment After Final Rejection was filed July 17, 2002. In the Advisory Action (Paper 15) mailed August 13, 2002, the Examiner advised applicants that the Amendment After Final would be entered upon filing an appeal. A supplemental amendment was filed July 7, 2003 to clarify the status of the claims.

5. SUMMARY OF INVENTION

The present invention is directed to a method for determining an initial flow rate of liquid in a conduit (Figure 1, Reference 10; Page 7, Lines 9-19), comprising:

(a) introducing a discrete known volume over a known time to the initial flow rate (Q_i in Figure 1; Page 9, Lines 5-6; Page 13, Equation 5);

(b) sensing a corresponding resulting change in the flow in the conduit (Page 9, Lines 9-19; Lines 20-24; Page 13, Lines 7-17) and;

(c) determining the initial flow rate in response to the introduced known volume, the known time and the sensed resulting change. (Page 3, Lines 3-4; Page 3, Lines 20-23; Page 9, Lines 20-24; Page 10, Lines 1-8; Page 13, Lines 7-17)

6. ISSUES

1. Whether Claims 1-5, 7-10, 20-22 and 25 are properly rejected under 35 U.S.C. §102(b) as being anticipated by Baumann, *et al.* (US Patent No. 5,792,963).

2. Whether Claims 6, 11-19, 23, 24 and 26-33[1] are properly rejected under 35 U.S.C. §103 over Baumann in view of Krivitski *et al.* (US Patent No. 5,685,989).

7. GROUPING OF CLAIMS

Claims 1-3, 5, 7, 8, 9, 10 and 34 stand or fall together.

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[1] Although the Office Action (Paper 19) expressly states "6, 11-19, 23, 24 and 26-33" are rejected under 35 USC 103, applicants assume "33" is a typo, meant to be "38".

Claim 4 stands or falls alone.

Claim 6 stands or falls alone.

Claims 11-14, 16-19 and 35 stand or fall together.

Claim 15 stands or falls alone.

Claims 20-21 stand or fall together.

Claim 22 stands or falls alone.

Claim 23 stands or falls alone.

Claim 24 stands or falls alone.

Claim 25 stands or falls alone.

Claims 26-33 stand or fall together.

Claim 36 stands or falls alone.

Claim 37 stands or falls alone.

Claim 38 stands or falls alone.

8. ARGUMENT

(i) Rejections Under 35 U.S.C. §112, First Paragraph

There are no outstanding rejections under 35 U.S.C. §112, first paragraph.

(ii) Rejections Under 35 U.S.C. §112, Second Paragraph

There are no outstanding rejections under 35 U.S.C. §112, second paragraph.

(iii) Rejections Under 35 U.S.C. §102

Claims 1-5, 7-10, 20-22 and 25 stand rejected under 35 U.S.C. §102(b) as being anticipated by Baumann U.S. Patent No. 5,792,963 (the '963 patent).

In supporting the rejection, Examiner Dickens cites Baumann for a number of disclosures. Applicants respectfully disagree with such interpretation of Baumann. A number of the assertions made by the Examiner are addressed in the following sections.

Determining an initial flow rate ... in a conduit

Examiner Dickens asserts "Baumann et al. teaches an apparatus used in the method of determining *an initial flow rate* of a liquid in a conduit comprising:" [emphasis added] [Paper 19, page 2].

In contrast, Baumann is directed to determining a total mass flow of a gas mixture, wherein the gas mixture includes the initial flow <u>and</u> the introduced tracer gas. This is not the initial flow rate, but rather the resulting gas mixture flow rate.

The gas mixture in Baumann is the steam from the turbine <u>and</u> the introduced tracer gas (O_2). Specifically,

> 1. Field of the Invention
> The invention relates to a method for determining the total mass flow of a gas mixture flowing through a line under vacuum, by using as tracer a gas contained in this gas mixture, the components of the gas mixture being known.

(Col. 1, lines 5-10)

> The molar proportions of the tracer and the mass balances of the total system and of the tracer, which are determined from the pressure measurements, in particular make it possible to calculate the total mass flow of the gas mixture.

(Col. 1, lines 40-45)

In fact, the claims of Baumann are directed to total mass flow of a gas mixture:

> 1. A method for determining the total mass flow of a gas mixture flowing through a line under vacuum, by using a known component of the gas mixture as a tracer, comprising the sequential steps of:

(Col. 4, lines 34-37)

There is no disclosure or suggestion of measuring the initial flow rate (the flow rate prior to the addition of the tracer gas). Baumann only determines the gas mixture flow rate. Therefore, Baumann cannot support the assertion of teaching "an apparatus used in the method of determining *an initial flow rate* of a liquid and a conduit."

*Determining an initial flow rate **of a liquid** in a conduit*

Examiner Dickens asserts "Baumann et al. teaches an apparatus used in the method of determining an initial flow rate *of a liquid* in a conduit comprising:" [emphasis added] [Paper 19, page 2].

Applicants respectfully submit Baumann does not disclose or suggest "determining an initial flow rate *of a liquid* in a conduit." [emphasis added] Baumann states:

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1

**METHOD FOR DETERMINING GAS MASS
FLOWS BY USE OF A TRACER GAS**

</div>

1. Field of the Invention
The invention relates to a method for determining the total mass flow of a gas mixture flowing through a line under vacuum. by using as tracer a gas contained in this gas mixture. the components of the gas mixture being known. (Col. 1, lines 6-10)

Accordingly. one object of the invention is to provide a novel method. with which the gas mass flows components are first known. (Col. 1, lines 28-30)
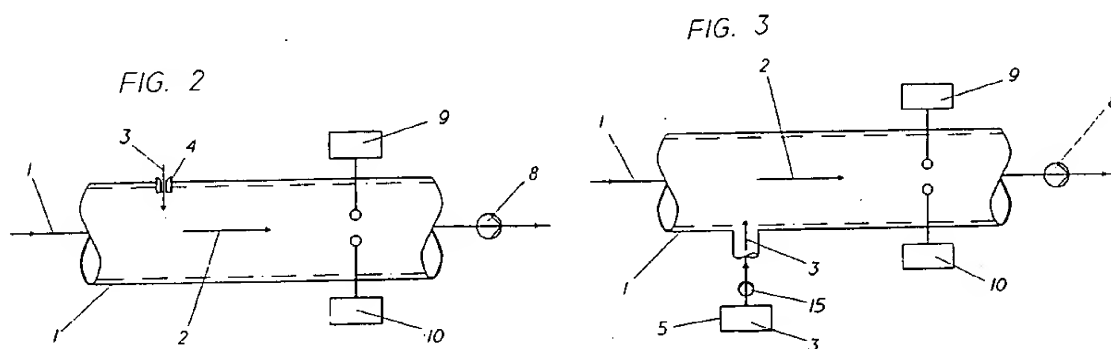
The molar proportions of the tracer and the mass balances of the total system and of the tracer. which are determined from the pressure measurements. in particular make it possible to calculate the total mass flow of the gas mixture. (Col. 1, lines 40-44)

This is not a determination of the flow rate of a *liquid*.

Introducing a discrete known volume over a known time to the initial flow rate in the conduit

The Examiner asserts Baumann discloses "introducing a discrete known volume over a known time to the initial flow rate in the conduit." [Paper 19, page 3] To support this assertion, the Examiner cites Figures 2 and 3. However, neither the figures nor the written description of Baumann disclose or suggest "introducing a discrete known volume over a known time to the initial flow rate in the conduit."

Figures 2 and 3 of Baumann disclose:

FIG. 2

FIG. 3

This does not disclose introducing a discrete known volume over a known time. No portion of Baumann has been cited to disclose the introduction of a discrete known volume over a known time. Even if the pump 15 is relied upon, there is no disclosure of a discrete known volume over a known time.

Withdrawing a discrete volume from the conduit

The Examiner asserts Baumann discloses "withdrawing a discrete volume from the conduit (col. 2, lines 16-19)" [Paper 19, page 3]. However, this section of Baumann recites:
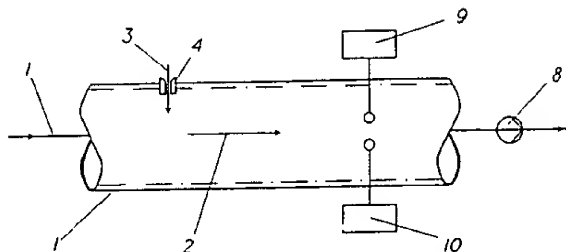
> **The way of ascertaining the mass flow in the suction line 1 is now explained with the aid of the exemplary embodiment in FIG. 2, in which a constant tracer molar flow 3 flow into the line through a critical orifice 4.**
> (Col. 2, lines 16-19)

Referring to Figures 2 and 3 of Baumann, the suction line 1 is the line in which the gas mixture is measured. There is no withdrawal of a discrete volume from the suction line 1. The suction line 1 cannot be both the measured gas mixture and the

withdrawn amount. As seen in Figure 2 of Baumann, the suction line 1 is actually the pipe in which the gas mixture is measured.

FIG. 2

Sensing an upstream location and a downstream location

The Examiner relies upon Figures 2 and 3 of Baumann to disclose sensing an upstream location and a downstream location. [Paper 19, page 3]

In Baumann, the sensors 9 and 10 are a total pressure monitor 9 and an oxygen partial pressure monitor 10. The flow, shown in Figures 2 and 3 of Baumann, extends horizontally. Therefore, the sensors 9 and 10 are disposed at a common longitudinal position and cannot provide sensing an upstream location and a downstream location, as asserted by the Examiner.

Using one of flow, velocity, optical ... sensors

The Examiner asserts Baumann in Col. 2, lines 35-44 discloses sensing the flow "using one of flow, velocity, optical and pressure sensors" [Paper 19, page 3] The cited section of Baumann is reproduced below:

Two series of measurements are first carried out in the suction line 1 under vacuum. In this case the gas mixture total pressure is determined using a pressure-measurement system 9 and the partial pressure of the oxygen, which is 40 here used as tracer and is referred to thus below, is determined using a pressure-measurement system 10. The pressure-measurement system 9 is a barometric standard pressure-measurement system and the pressure-measurement system 10 is an oxygen partial-pressure gage. (Col. 2)

Bowman discloses a partial pressure measurement system, including the partial pressure of oxygen, such as a barometric standard pressure measurement system and an oxygen partial pressure gage. There is no disclosure of:

1. a velocity sensor;

2. an optical sensor; or

3. a flow sensor.

Determining the initial flow rate in response to the introduced volume change and the sensed resulting change

The Examiner asserts Baumann at column 2, lines 36-44 discloses "determining the initial flow rate in response to be introduced following change and the sensed resulting change" [Paper 19, page 3]. The cited section of Baumann is:

> Two series of measurements are first carried out in the suction line 1 under vacuum. In this case the gas mixture total pressure is determined using a pressure-measurement system 9 and the partial pressure of the oxygen, which is
> 40 here used as tracer and is referred to thus below, is determined using a pressure-measurement system 10. The pressure-measurement system 9 is a barometric standard pressure-measurement system and the pressure-measurement system 10 is an oxygen partial-pressure gage. (Col. 2)

This does not disclose or suggest determining the initial flow rate in response to the introduced known volume over a known time and the sensed resulting change.

Further, as set forth above, Baumann determines the total mass flow of gas mixture, rather than an initial flow rate.

Claims 1-3, 5, 7, 8, 9, 10 and 34

Claims 1-3, 5, 7, 8, 9, 10 and 34 recite in part "introducing a discrete known volume over a known time to the initial flow rate."

As set forth above, Baumann does not disclose or suggest introducing a discrete known volume over a known time to the initial flow rate. Rather, Baumann allows an unmeasured introduction of air into the flow within suction line 1. The Examiner has not identified any portion of Baumann disclosing introducing a discrete known volume over a known time to the initial flow rate. The absence of this limitation precludes Baumann from sustaining the asserted rejection under 35 U.S.C. §102.

Claims 1-3, 5, 7, 8, 9, 10 and 34 further recite in part "determining the initial flow rate in response to the introduced known volume, the known time and the sensed resulting change."

As set forth above, Baumann measures the total mass flow of a gas mixture flowing through the suction line, rather than the initial flow (the flow prior to introduction of the tracer gas). The absence of this limitation precludes Baumann from sustaining the asserted rejection under 35 U.S.C. § 102.

Therefore, applicants respectfully submit Claims 1-3, 5, 7, 8, 9, 10 and 34 are in condition for allowance.

Claim 4

Claim 4 depends from independent Claim 1 and further recites "sensing at an upstream location to the introduced volume and a downstream location to the introduced volume."

As stated above, Baumann employs two pressure sensors at a common longitudinal position along the flow path. Therefore, Baumann cannot disclose sensing at an upstream location and a downstream location. The absence of at least this limitation precludes Baumann from sustaining the asserted rejection under 35 USC § 102.

Further, both Baumann sensors are downstream of the introduced tracer gas (via the orifice 4 in Figure 3). Thus, all the sensing of Baumann is only performed downstream of the introduced tracer gas. There is no sensing upstream of the introduced volume. The absence of at least this limitation precludes Baumann from sustaining the asserted rejection under 35 USC § 102.

Claims 20-21

Claims 20 and 21 recite in part "introducing a discrete known volume over a known time to the initial flow in the conduit to produce a resulting change in the initial flow."

Baumann does not disclose "introducing a discrete known volume." Rather Baumann introduces an unmeasured volume of ambient air or operates the pump. This is not a discrete known volume. At best, it is a continuous introduction, but it is not a discrete known volume. The absence of this limitation precludes Baumann from sustaining the rejection under 35 USC §102.

Baumann does not disclose introducing a discrete known volume "over a known time." Rather, Baumann vents the low pressure suction line 1 to ambient air, without measuring the time (or duration) of the introduction. This is not an introduction over a known time. The absence of this limitation precludes Baumann from sustaining the rejection under 35 USC §102.

Claims 20 and 21 further recite in part "determining the initial flow rate in response to the introduced discrete known volume, the known time and the resulting change."

As previously set forth, Baumann measures the total mass flow of the resulting gas mixture, and not the initial flow within the suction line 1. Therefore, this limitation is also absent from Baumann.

The absence of at least these limitations precludes Baumann from sustaining the asserted rejection of Claims 20 and 21 under 35 USC §102.

Claim 22

Independent Claim 22 recites in part "means for introducing a discrete known volume over a known time to the initial flow."

Baumann vents the suction line 1 to atmospheric pressure through orifice 4 or operates the pump, without any indication of a known flow rate or duration of the venting. There is no time control; and thus, Baumann does not disclose "means for introducing a discrete known volume over a known time to the initial flow." The absence of this limitation precludes Baumann from sustaining the asserted rejection under 35 U.S.C. §102.

Claim 22 further recites in part "a controller connected to the sensor, the controller configured to determine the initial flow rate in a response to the known volume, the known time and the corresponding change."

As Baumann does not determine the initial flow rate, but rather the resulting gas mixture flow rate, there can be no "controller configured to determine the initial flow rate in response to the known volume, known time and corresponding change."

The absence of at least these limitations precludes Baumann from sustaining the asserted rejection under 35 U.S.C. §102.

Claim 25

Independent Claim 25 recites in part "a known flow rate introducer selected to effect a discrete known flow rate to produce a resulting change in the initial flow in the conduit."

The orifice 4 of Baumann is not a known flow rate introducer selected to effect a discrete known flow rate. Baumann does not disclose the size of the orifice 4, the velocity of the flow through the orifice 4, or the pressure differential across the orifice 4 which would be required to determine a flow rate through the orifice 4. Therefore, Baumann cannot be construed to disclose a known flow rate introducer. Further, a constant volume pump does not provide the necessary known flow rate.

Claim 25 further recites in part "a controller connected to the sensor, the controller configured to determine the initial flow rate in response to the known flow rate and the resulting change measured by the sensor."

As Baumann (1) does not determine the initial flow rate; and (2) does not provide a known flow rate, there can be no controller configured to determine the initial flow rate in response to the known flow rate and the resulting change measured by the sensor.

The absence of at least these limitations precludes Baumann from sustaining the asserted rejection under 35 U.S.C. §102.

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(iv) Rejections Under 35 U.S.C. §103

Claims 6, 11-19, 23, 24 and 26-33[2] are rejected under 35 U.S.C. §103 over Baumann in view of Krivitski *et al.* (US Patent No. 5,685,989).

Examiner Dickens asserts these claims differ from Baumann by the recitations of a catheter in determining the blood flow rate in a conduit. [Paper 19, pages 3-4]

Applicants respectfully reassert the distinctions between Baumann and the independent claims, as set forth in the argument with respect to the rejections under 35 U.S.C. §102.

Examiner Dickens asserts "It would have been obvious to one of ordinary skill in the art at the time the invention was made to have a catheter in determining the blood flow rate in a conduit in Baumann et al. as is taught by Krivitski et al. for the purpose of measuring blood flow and recirculation and hemodialysis shunts." [Paper 19, page 4]

To sustain the rejection under 35 U.S.C. §103, the Board must "explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious." *In re Lee*, 61 USPQ2d 1430, 1434 (Fed. Cir. 2002). [emphasis added]

Applicants submit there is no objective evidence presented why one of ordinary skill in the art would modify a method for determining gas mass flows in a gas turbine generator carrying a gas mixture under vacuum, with a medical apparatus for measuring recirculation and hemodialysis patient shunts.

"A prerequisite to making a finding on the scope and content of the prior art is to determine what prior art references are pertinent." *In re Clay*, 966 F.2d 656, 658 23 USPQ2d 1058 (Fed. Cir. 1992). Whether a prior art reference is analogous is a question of fact. *Id.* A reference is analogous if it is from the same field of endeavor as the invention. *Id.* at 658-59. Similarity in the structure and function of the invention and the

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[2] Although the Office Action (Paper 19) expressly states "6, 11-19, 23, 24 and 26-33" are rejected under 35 USC 103, applicants assume "33" is a typo, meant to be "38".

prior art is indicative that the prior art is within the inventor's field of endeavor. *In re Deminski*, 796 F.2d 436, 442 230 USPQ 313 (Fed. Cir. 1986). If a reference is outside the inventor's field of endeavor, it is still analogous art if the reference "is reasonably pertinent to the particular problem with which the inventor is involved." *Clay*, 966 F.2d at 659." *State Contracting & Engineering Corp. v. Condotte America Inc.*, 68 USPQ2d 1481 (Fed. Cir. 2003)

Measurement of gas turbine discharge is not the same field of endeavor as determining a blood flow in a conduit, or using a catheter. Further, the Examiner has not provided a basis for combining the measurement of a gas mixture with the determination of an initial blood flow.

The lack of this showing precludes the rejection under 35 U.S.C. § 103 from being sustained.

Applicants respectfully submit, the "obvious" standard is at best strained by the assertion that one would modify a turbine exhaust flow measurement system to have a catheter for determine blood flow rate in hemodialysis shunts.

Further, the proposed combination of references would still not provide the claimed limitations. That is, to locate a catheter in the Baumann conduit (which is downstream of a gas turbine) would hardly provide the asserted measuring of an initial blood flow.

These deficiencies render the proposed combination and rejections under 35 U.S.C. § 103 legally insufficient.

"The examiner can satisfy the burden of showing obviousness of the combination 'only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references'" *In re Lee*, 61 USPQ2d 1430, 1434 (Fed. Cir. 2002).

Claim 6

Claim 6 depends from Claim 1 and recites in part "introducing the discrete known volume over a known time through a catheter in the conduit."

As previously stated, the Examiner has not provided any objective evidence or objective basis for introducing a known volume over a known time (which is not disclosed by the primary reference Baumann nor the secondary reference Krivitski) through a catheter in the conduit of Baumann.

Further, the Examiner has not provided any basis for employing a catheter within the suction line 1 of Baumann. No basis has been provided for modifying the orifice 4 of Baumann to become a catheter. In addition, introduction of the ambient air in Baumann through a catheter, as opposed to the orifice 4 of Baumann, would seem to have little change in the process of Baumann – and certainly not disclose or suggest the present limitations.

Also neither of the cited references disclose the limitation of "introducing the discrete known volume over a known time through a catheter in the conduit." This distinction from Krivitski was set forth in the prior Appeal Brief and for Baumann in the analysis of the rejections under 35 USC §102.

Therefore, applicants respectfully submit the rejection under 35 U.S.C. §103 of Claim 6 cannot be sustained.

Claims 11-14, 16-19 and 35

Claims 11-14, 16-19 and 35 recite in part "introducing a known flow rate to the initial flow rate through the catheter."

Neither the primary reference nor Baumann nor the secondary reference Krivitski disclose introducing a known flow rate to the initial flow rate.

Neither reference discloses "determining the initial flow rate in response to the introduced known flow rate and the resulting change in the initial flow rate."

Applicants further submit neither reference discloses introducing the recited know flow rate through a catheter.

As the cited references do not disclose or suggest each of the limitations of these claims, applicants respectfully submit the rejection of these claims under 35 U.S.C. §103 cannot be sustained. In addition, the asserted combination of references being contrary to both the primary and secondary reference, as well as failing to provide the recited claim limitations, cannot sustain the asserted rejection under 35 U.S.C. §103.

Claim 15

Claim 15 depends from Claim 11 and further recites "sensing at an upstream location to the introduced known flow rate and a downstream location to the introduced known flow rate."

As set forth in the argument with respect to rejections under 35 U.S.C. §102, the sensors 9 and 10 of Baumann are located at a common longitudinal position along the flow through the suction line 1. There are no sensors located in a relative upstream and downstream position.

Further, Baumann does not contemplate, nor can provide, any basis for measuring upstream to the orifice 4. Therefore, applicants respectfully submit the asserted rejection under 35 U.S.C. §103 cannot be sustained.

Claim 23

Claim 23 depends from Claim 22 and includes the limitations thereof, and further recites in part "a catheter having an introduction port."

As neither reference discloses nor suggests means for introducing a discrete known volume over a known time, nor means for introducing a discrete known volume over a known time in combination with a catheter having an introduction port, the asserted rejection under 35 U.S.C. §103 cannot be sustained.

Claim 24

Claim 24 depends from Claim 23 and includes all the limitations thereof, and further recites in part "the sensor is connected to the catheter."

The Examiner has not provided any suggestion to employ a catheter in the turbine exhaust line of Baumann or include the sensor on such catheter. The only basis asserted is the present disclosure and as such is legally insufficient. Therefore, the asserted rejection of Claim 24 under 35 U.S.C. §103 cannot be sustained.

Claims 26-33

Claims 26-33 recites in part "introducing a known flow rate of an indicator into the conduit to create a discrete volume change in the initial flow and a liquid characteristic change in the conduit."

As neither reference discloses nor suggests this limitation, the rejection under 35 U.S.C. § 103 cannot be sustained.

Claims 26-33 further recite "optically sensing the liquid characteristic change in the conduit with a sensor located external to the conduit."

As Baumann expressly employs pressure sensors 9, 10 located within the flow stream, applicants respectfully submit this limitation of optically sensing with a sensor external to the conduit cannot be obvious in view of the cited references.

Claims 26-33 also recite "determining the initial blood flow rate in the conduit in response to the introduced known flow rate of indicator and the sensed liquid characteristic change."

The failure of either reference to disclose this limitation precludes a rejection of Claims 26-33 under 35 U.S.C. §103.

Claim 36

Claim 36 depends from Claim 20 and further recites in part "wherein one of the known volume and the known time is determined by measuring."

The Examiner has not provided any basis in either reference, nor in the combination of references for introducing a discrete known volume over a known time to the initial flow. Therefore, there is no disclosure of measuring one of the known volume and the known time.

As the limitations of Claim 36 are not disclosed or suggested in the references, either individually or in combination, and the proposed combination references would be contrary to the primary reference, applicants respectfully submit the rejection of Claim 36 cannot be sustained.

Claim 37

Independent Claim 37 recites in part "determining an initial blood flow rate Q" corresponding to five relationships. Each relationship sets forth a dependence of Q to Q_i, where Q_i is the introduced flow rate.

Again, as Examiner Dickens has not identified any portion of the cited references, either individually or in combination which set forth a known introduced flow rate, this rejection cannot be sustained.

Claim 38

Independent Claim 38 recites in part "determining the initial flow rate Q, corresponding to an introduced flow rate to the initial flow rate."

The introduced flow rate is defined as a given volume over a given time. The venting of the suction line 1 of Baumann to atmospheric pressure does not, alone or in combination with Krivitski, disclose or suggest determining an initial flow rate corresponding to an introduced flow rate.

(v) There are no other outstanding grounds of rejection not covered by Paragraphs (i) - (iv).
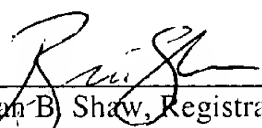
CONCLUSION

At least the following factors require that the outstanding rejection of Claims 1-38 be reversed:

1. Baumann does not disclose determining an initial flow rate.

2. Baumann does not disclose determining an initial flow rate of a liquid.

3. Baumann does not disclose introducing a known volume over a known time.

4. Baumann does not disclose withdrawing a discrete volume.

5. Baumann does not disclose a flow, velocity or optical sensor.

6. Baumann is not properly combined with Krivitski.

7. Krivitski cannot cure the deficiencies of Baumann.

Therefore, applicants respectfully request the Board to reverse each of the outstanding rejections.

Respectfully submitted,

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Date: February 19, 2004

1. A method for determining an initial flow rate of a liquid in a conduit, comprising:

(a) introducing a discrete known volume over a known time to the initial flow rate;

(b) sensing a corresponding resulting change in the flow in the conduit; and

(c) determining the initial flow rate in response to the introduced known volume, the known time and the sensed resulting change.

2. The method of Claim 1, wherein introducing the discrete known volume over the known time includes injecting or withdrawing the discrete volume from the conduit.

3. The method of Claim 1, further comprising employing one of a flow characteristic sensor and a liquid characteristic sensor.

4. The method of Claim 1, wherein sensing the corresponding resulting change includes sensing at an upstream location to the introduced volume and a downstream location to the introduced volume.

5. The method of Claim 1, wherein sensing the corresponding resulting change includes employing a sensor located at one of in the conduit, on the conduit or spaced from an exterior of the conduit.

6. The method of Claim 1, wherein introducing the discrete known volume over a known time includes introducing the discrete known volume over a known time through a catheter in the conduit.

7. The method of Claim 1, further comprising sensing the corresponding resulting change in one of a liquid characteristic and a flow characteristic.

8. The method of Claim 1, wherein sensing a corresponding resulting change includes sensing a corresponding resulting change proportional to the flow in the conduit.

9. The method of Claim 1, wherein sensing a corresponding resulting change includes sensing one of a velocity, pressure and flow rate of the flow in the conduit.

10. The method of Claim 1, wherein sensing a corresponding resulting change includes sensing a dilution indicator.

11. A method for determining an initial flow rate in a conduit, comprising:

(a) locating a catheter in the conduit;

(b) introducing a known flow rate to the initial flow rate through the catheter; and

(c) determining the initial flow rate in response to the introduced known flow rate and a resulting change in the initial flow rate.

12. The method of Claim 11, wherein introducing a known flow rate includes introducing a discrete volume change.

13. The method of Claim 11, wherein introducing a known flow rate includes injecting or withdrawing a discrete volume from the conduit.

14. The method of Claim 11, further comprising employing one of a flow characteristic sensor and a liquid characteristic sensor.

15. The method of Claim 11, wherein sensing the corresponding resulting change includes sensing at an upstream location to the introduced known flow rate and a downstream location to the introduced known flow rate.

16. The method of Claim 11, wherein sensing a corresponding resulting change includes sensing with a sensor located at one of in the conduit, on the conduit or spaced from an exterior of the conduit.

17. The method of Claim 11, further comprising sensing a resulting change after introducing the known flow rate.

18. The method of Claim 17, wherein sensing the resulting change includes sensing a change corresponding to the introduced known flow rate in one of a liquid characteristic and a flow characteristic.

19. The method of Claim 17, further comprising sensing a resulting change as proportional to the flow in the conduit.

20. A method for determining an initial flow rate in a conduit, comprising:

(a) introducing a discrete known volume over a known time to the initial flow in the conduit to produce a resulting change in the initial flow; and

(b) determining the initial flow rate in response to the introduced discrete known volume, the known time and the resulting change.

21. The method of Claim 20, further comprising employing a sensor to sense the resulting change in the flow.

22. An apparatus for determining an initial flow rate in a conduit, comprising:

(a) means for introducing a discrete known volume over a known time to the initial flow;

(b) a sensor for measuring a corresponding change resulting from the introduced discrete known volume over the known time; and

(c) a controller connected to the sensor, the controller configured to determine the initial flow rate in a response to the known volume, the known time and the corresponding change.

23. The apparatus of Claim 22, further comprising a catheter having an introduction port.

24. The apparatus of Claim 23, wherein the sensor is connected to the catheter.

25. An apparatus for determining an initial flow rate in a conduit, comprising:

(a) a known flow rate introducer selected to effect a discrete known flow rate to produce a resulting change in the initial flow in the conduit;

(b) a sensor for measuring the resulting change; and

(c) a controller connected to the sensor, the controller configured to determine the initial flow rate in a response to the known flow rate and the resulting change measured by the sensor.

26. A method for determining an initial blood flow rate in a conduit, comprising:

(a) introducing a known flow rate of an indicator into the conduit to create a discrete volume change in the initial flow and a liquid characteristic change in the conduit;

(b) optically sensing the liquid characteristic change in the conduit with a sensor located external to the conduit; and

(c) determining the initial blood flow rate in the conduit in response to the introduced known flow rate of indicator and the sensed liquid characteristic change.

22/25

27. The method of Claim 26, wherein introducing the known flow rate of the indicator includes introducing a change in blood hematocrit in the conduit.

28. The method of Claim 26, wherein introducing the known flow rate of the indicator includes introducing a solution including at least one of saline and glucose into the conduit.

29. The method of Claim 28 further comprising introducing an isotonic solution into the conduit.

30. The method of Claim 26, wherein optically sensing the liquid characteristic change includes obtaining a value proportional to the liquid characteristic change.

31. The method of Claim 26, wherein introducing the volume of the indicator into the conduit includes introducing the known flow rate of indicator upstream of an area sensed by the optical sensor.

32. The method of Claim 26, wherein the liquid characteristic is blood hematocrit.

33. The method of Claim 26, wherein optically sensing the liquid characteristic change includes obtaining a value proportional to blood hematocrit in the conduit.

34. The method of Claim 1, further comprising measuring to identify one of the known volume and the known time.

35. The method of Claim 11, further comprising determining the known flow rate by measuring.

36. The method of Claim 20, wherein one of the known volume and the known

time is determined by measuring.

37. A method for determining an initial blood flow rate in a conduit,

comprising:

(a) determining the initial blood flow rate Q, corresponding to at least one

of the following and an analogous relationships:

$$Q = \frac{Q_i}{\left(\dfrac{\Delta Q_d}{Q_d} - \dfrac{\Delta Q_u}{Q_u} \right)} ; \quad Q = \frac{Q_i}{\left(C_{bd} - C_{bu} \right)} ; \quad Q = \frac{Q_i}{\left(\dfrac{\Delta V_d}{V_d} - \dfrac{\Delta V_u}{V_u} \right)} ;$$

$$Q = \frac{Q_i}{\left(\dfrac{\Delta hu}{hui} - \dfrac{\Delta hd}{hdi} \right)} ; \quad Q = \frac{Qi}{\left(\dfrac{\Delta Pd}{Pd - Pven} - \dfrac{\Delta Pu}{Pu - Part} \right)}$$

where Q_i is the introduced volume during the introduced time;

$\Delta Q_d = Q_{di} - Q_d$;

$\Delta Q_u = Q_{ui} - Q_u$;

Q_d is the flow rate downstream of an introduction point of Q_i;

Q_u is the flow rate upstream of an introduction point of Q_i;

C_{bd} is the relative change in a flow corresponding parameter from an upstream

volume injection;

C_{bu} is the relative change in a flow corresponding parameter from a downstream

volume injection;

ΔV_u is a change corresponding to an upstream blood velocity;

ΔV_d is a change corresponding to a downstream blood velocity;

V_u is an upstream blood velocity;

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V_d is a downstream blood velocity;

hu is a concentration of indicator measured at an upstream sensor;

hd is a concentration of indicator measured at a downstream sensor;

$\Delta hu = hui-hu$; and

$\Delta hd = hdi-hd$.

38. A method for determining an initial blood flow rate in a conduit, comprising:

(a) determining the initial blood flow rate Q, corresponding to an introduced flow rate to the initial flow rate.